K121761

SEP 2 8 2012

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for a 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Applicant:	Tomed Dr. Toussaint GmbH Wiesenstr. 4 Bensheim, Germany D-64625 Phone: +49 6251 98 33 44 Facsimile: +49 6251 98 33 45
Establishment Registration Number:	3006038700
Manufacturing/ Distribution Address:	Tomed Dr. Toussaint GmbH Wiesenstr. 4 Bensheim, Germany D-64625
US Contact:	Scott Whitcomb, President/CEO 1st Line Medical, Inc. 854 US Route 3 Holderness, NH 03245 Phone: 603-968-3172 Facsimile: 603-968-3158 E-mail: SWhitcomb@1stLineMedical.com
Date submitted:	May 21, 2012
Proprietary Name:	SomnoGuard® SP Soft[1]
Common Name:	Anti-Snoring / Sleep Apnea Device
Classification Status:	Class II per regulations §872.5570
Product Codes:	LRK,
Predicate Devices:	• SomnoGuard® AP (K061688), Tomed Dr. Toussaint GmbH • SilentNite® (K972424), Glidewell Laboratories

[1] In some countries there is a second model of SomnoGuard® SP, named SomnoGuard® SP Hard. Both models differ in the thermoplastic impression material only. SomnoGuard® SP Hard uses PCL (Polycaprolactone) instead of Elvax, giving a higher retention. SomnoGuard® SP Hard is not intended to be sold in the U.S.

Device Description

The entire family of SomnoGuard mandibular advancement devices is used for treating snoring and mild to moderate obstructive sleep apnea. The principal effect of all appliances is the advancement of the lower jaw, thereby opening the upper airway and reducing snoring and the breathing arrests due to mild to moderate obstructive sleep apnea.

SomnoGuard can be fitted without the need of taking a patient's dental impressions as a prerequisite to construct the ready-to-use device. SomnoGuard devices are "boil-&-bite" appliances. To prepare fitting of the appliance it is necessary to heat the appliance in hot water that has been boiled for approximately 3:30 seconds. Thereafter, when the device is removed from the hot water and has cooled down for about 10 seconds, a physician or his or her trained staff inserts the device into the mouth of the patient, thereby first the lower jaw into the lower arch, then the upper jaw into the upper channel of the device. The patient then puts forward his or her lower jaw commonly at normal bite conditions to approximately half the maximum extension possible, with the plastic still warm and mouldable, and then firmly bites the plastic. When doing this, patient sucks in while closing the mouth and pressing the tongue against the inner surface of the front teeth. In parallel, doctor presses his or her fingers on the outer walls of the mouthpiece to make sure that the appliance is properly moulded. The process is completed by fixing the bite impression by rinsing the device in cold water.

Boil-&-bite appliances are primarily considered by sleep specialists and dentists for short-term use up to about one year or as a first-line screening device to determine whether patients suffering from snoring and / or mild to moderate obstructive sleep apnea (OSAS) respond positively to oral appliance therapy, the outcome of which cannot be predicted for any appliance available in the marketplace prior to its usage. Thus in case of no therapeutic effect larger investments for the much more expensive custom dental lab made appliances can be avoided.

SomnoGuard® AP (AP = Adjustable Positioner) as well as SomnoGuard® SP Soft (SP = Sagittal Positioner) are two-part infinitely adjustable appliances enabling a protrusion of up to 10 mm, allowing lateral lower jaw movement and breathing through the mouth whenever needed. The devices consist of two independent trays each with a thermoplastic body, and both parts linked to each other by a coupling protrusion mechanism. The outer tray shells consist of solid, clear and transparent medical grade polycarbonate. The inner lining which

accommodates the teeth impressions is made of a thermoplastic copolymer which is similar to that used with the previously FDA cleared SomnoGuard® one-part appliances. After the oral appliance is heated in a hot water bath its thermoplastic body moulds easily to the teeth and jaws allowing any medical doctor to very easily fit the device chair side.

The SomnoGuard® SP Soft two connectors, made out of Polyoxymethylene (POM), connect the lower and the upper part of the appliance. Each device comes with 6 connectors of different length, enabling individual protrusion of up to 10 mm.

With the SomnoGuard® AP an adjusting screw made of stainless steel allows the anterior adjustment of the lower tray against the upper tray between 0 and about 10 mm or even more depending on the length of the screw used. The adjustment is only possible extra-orally and when the upper and lower trays are disassembled. Disassembling both trays is also necessary for cleaning.

The highly cost-effective device is considered for medium term use up to two years.

All "boil-&-bite" appliances are simple to fit by dentists and other medical specialists, taking about 10 minutes and not requiring any special tools. Since compliance and treatment outcomes cannot be predicted with any oral appliance currently available in the marketplace as previously mentioned, it always makes sense from a cost and economical point of view to initiate treatment with a more economical boil & bite device before subjecting patients to a much larger investment for the fabrication of a custom made dental appliances such as the SomnoGuard AP Pro.

Intented Use Statement

The SomnoGuard® SP Soft is intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea (OSAS) in adults.

Comparison of Predicate Devices

SomnoGuard® SP Soft and SomnoGuard® AP use identical materials for the thermoflexible impression material and the hard shell trays but have different connectors between the upper and lower jaw trays.

SomnoGuard® SP Soft and SilentNite® are made out of different materials and SilentNite® is individually made but they share the same connecting mechanism out of the same materials between the upper and the lower jaw trays.

All devices have an identical intended use, the reduction or alleviation of night-time snoring and mild to moderate obstructive sleep apnea in adults.

Substantial equivalence is based on non-clinical data as it relates to the historical significance of oral devices that reposition the jaw and reduce or manage snoring. Pancer et al. described this in an article published in the journal CHEST in 1998, where they concluded that mandibular advancement devices (MAD) were 95% successful in reducing and/or controlling snoring. In addition the American Academy of Sleep Medicine (formerly the American Sleep Disorders Association) published in 1995 their Standards of Practice and Guidelines which demonstrated that oral appliances were effective in the management of snoring.

Clinical Data

Own clinical data from clinical studies in Germany, the U.S. and Belgium, as well a numerous number of articles referring to other MADs repeatedly looked at oral appliances and their use for the treatment of snoring confirm that oral appliance therapy is an effective means by which snoring can be managed and breathing arrests due to mild to moderate obstructive sleep apnea can be reduced. This effectiveness is embraced from a variety of aspects including safety, convenience and cost.

In conclusion, a number of studies have shown improvement of the airway utilizing imaging associated with the use of oral appliances (also referred to as Oral Airway Dilators), which aids in the management and reduction of snoring as well as breathing arrests due to mild to moderate obstructive sleep apnea.

Clinical and nonclinical data indicate that SomnoGuard® SP Soft is safe and effective for its intended use and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 28 2012

Tomed Dr. Toussaint GmbH
C/O Mr. Scott Whitcomb
President/Chief Executive Officer
1st Line Medical, Incorporated
854 US Route 3
Holderness, New Hampshire 03245

Re: K121761
Trade/Device Name: SomnoGuard® SP Soft
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: August 17, 2012
Received: September 12, 2012

Dear Mr. Whitcomb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121761

Device Name: SomnoGuard® SP Soft

Indications For Use: The SomnoGuard® SP Soft is a mandibular advancement device and is intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea (OSAS) in adults.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121761

Page 1 of __1__